UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,453	09/19/2003	David T. Hamrick	DSI-10202/22	7278

51279 7590 03/02/2006	EXAMINER
GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON & CITKOWSKI, P.C.	RAO, G NAGESH

	ART UNIT	PAPER NUMBER
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DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	10/665,453	HAMRICK ET AL.
	Examiner	Art Unit	
	G. Nagesh Rao	1722	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>23 September 2005</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-52</u> is/are pending in the application.

    4a) Of the above claim(s) <u>32 and 51</u> is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-31,33-50 and 52</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

Election/Restrictions

1)   Claims 32 and 51 withdrawn from further consideration pursuant to 37 CFR

1.142(b) as being drawn to a nonelected invention, there being no allowable

generic or linking claim. Election was made **without** traverse in the reply filed on

9/23/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2)   Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. What is meant by a process according to

claim 1 substantially as described herein in any of the examples. What examples,

and what constitutes an appropriate definition for substantially with respect to

claim 52?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102

that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3)   Claims 1-16, 18-19, 21-29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Levinson (US PG Pub 2002/0177167).

Levinson 167 pertains to a method and system for planning, peforming, and assessing high-throughput screening of multicomponent chemical compositions and solid forms of compounds.

Levinson 167 teaches an optimization process capable of being comprised of the following steps selecting a plurality of physical characterization input variables to define a total crystallization experiment permutation number for a crystallant, performing a plurality of crystallization experimental samples, said plurality of crystallization experimental samples being less than the total crystallization experiment permutation number, training a predictive crystallization function through analysis of said plurality of crystallization experimental samples, and determining an optimal physical crystallization parameter from said predictive crystallization function, and finally storing these optimal parameters and being capable of comparing an unknown crystallization sample to the classification

known and stored in the neural network taught in the specification (See Page 1

Section 0004, Page 3 Sections 0019-0025, and Page 4 Section 0039). Furthermore

the predictive crystallization function is a neural network, i.e. computer clusters

(Figure 6) wherein said crystallant could be a protein crystal wherein a plurality of

physical crystallization input variables could be temperature, protein, pH,

precipitation, etc...(See Page 19-20 Claims 24-27).

Furthermore the system taught by Levinson 167 would be capable of being

programmed and operating said permutation cycles, designating a status of

identification for the crystalline sample, creating and building from a database

developed for and by the system and its operators, being able to grow a crystal and

communicate predictive values/outcomes as understood by Levinson's 167 system

(See See Page 1 Section 0004, Page 3 Sections 0019-0025, and Page 4 Section

0039). Levinson 167 teaches a system not just a process, but a system that is more

than capable of handling the process put forth by applicants, particularly the fact

that the process put forth is programmed into a neural network as claimed by

applicant, the same neural network that Levinson 167 teaches and is more than

capable of automating and handling.

4)   Claims 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by

Levinson (US PG Pub 2002/0177167).

Levinson 167 teaches a neural network (See Figure 6) that is capable of

being trained through analysis of a plurality of crystallization experimental

samples to predict optimal crystallization conditions for a protein. Furthermore the

neural network could be programmed to be derive from the system a plurality of

samples comprised of samples failing to yield crystals, depends on the operator's

desired output.

5)   Claims 35-50 are rejected under 35 U.S.C. 102(e) as being anticipated by

Levinson (US PG Pub 2002/0177167).

As previously stated Levinson 167 teaches a system that can be programmed

and utilized for crystallization parameter optimization. The system may be

comprised of a database and an incomplete factorial screen program i.e.

programmed to handle such capabilities. However that is a recitation of intended

use with respect to the physical components and structure of the system such as the

computer (i.e. neural network), and manufacturing execution system that would be

comprised of a robotic handler, imaging system, dispenser, sample centering,

optical technology (See Page 9 Section 0066, 0076-0080). As argued before with

respect to claims 1-16, 18-19, 21-29 and 31, Levinson 167's system is capable of

doing so as claimed in claims 35-50, however this is a set of claims referring to the

system and not the process, a system that is capable and these further parameters

are recitation of intended use and bear no weight to the structural components of

the system itself.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102

that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6)   Claims 33-50 and 52 rejected under 35 U.S.C. 102(b) as being anticipated by

Gester PCT Pub WO99/04361.

Examiner would like to note that he is using Gester (US 6,529,612) as an

English equivalence to Gester PCT Pub WO99/04361.

Gester 612 pertains to a method and system for acquiring, storing, and

analyzing crystal images. Wherein the reference teaches among many other things

the following a data storage that reads on database and an incomplete factorial

screen program i.e. programmed to handle such capabilities. However that is a

recitation of intended use with respect to the physical components and structure of

the system such as the computer (i.e. neural network), and manufacturing

execution system that would be comprised of an automated mechanism system,

imaging system, dispenser, sample centering, optical technology (See Abstract,

Figures 1-6, Cols 3-5 Lines 1-68 and Col 6 Lines 1-39). Gester 612's system is

capable of doing as claimed in claims 35-50, however this is a set of claims

referring to the system and not the process, a system that is capable and these

further parameters are recitation of intended use and bear no weight to the

structural components of the system itself.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1.   Determining the scope and contents of the prior art.
2.   Ascertaining the differences between the prior art and the claims at
      issue.
3.   Resolving the level of ordinary skill in the pertinent art.
4.   Considering objective evidence present in the application indicating
      obviousness or nonobviousness.

7)   Claims 17, 20, and 30 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Levinson (US PG Pub 2002/0177167) in view of applicant's

admitted prior art on Pages 15 and 24 (Moloshok et. al. Application of Bayesian Decomposition for analyzing microarray data and Carter Jr. et. al. Protein crystallization using incomplete factorial experiments).

Levinson 167 teaches a neural network and a system that is more than capable along with a process for optimal crystallization parameter determination. It may explicitly fail to teach the use or implementation of a Chernov algorithm/analysis or a Bayesian net/classification schema. But it is more than capable of being programmed and operating such parameters as can be further reinforced by applicant's admittance of prior publications and art related to that field.

Therefore at the time of the invention it would be obvious to one with ordinary skill in the art to implement such an algorithmic and analysis operation system on the neural network devised along with the system for optimal crystallization parameter determination as taught by Levinson 167 to further optimize the processing conditions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to G. Nagesh Rao whose telephone number is (571) 272-2946. The examiner can normally be reached on 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Duane Smith can be reached on (571) 272-1166. The fax

phone number for the organization where this application or proceeding is assigned

is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR

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direct.uspto.gov. Should you have questions on access to the Private PAIR system,

contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GNR

ROBERT KUNEMUND
PRIMARY EXAMINER